

Express Mail No.: EV 038 541 235 US

PATENT  
PD-0294 DIV

**CUSTOMER NUMBER 23608**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of )  
Alfred E. Mann et al. ) Group Art Unit: Unknown  
Serial No. unknown )  
Filed: January 31, 2002 ) Examiner: Unknown  
For: EXTERNAL INFUSION DEVICE )  
WITH REMOTE PROGRAMMING, )  
BOLUS ESTIMATOR AND/OR )  
VIBRATION ALARM CAPABILITIES )

**PRELIMINARY AMENDMENT**

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

In connection with the above-identified application and prior to examination, please enter  
and consider the following preliminary amendment and remarks.

IN THE CLAIMS:

Please cancel claims 1-55 without prejudice or disclaimer, and add new claims 56-73 as follows (clean copies of the claims are provided at the end of the amendment):

--56. An external infusion system for infusion of a fluid into a body, the external infusion system comprising:

an infusion device for infusion of a fluid into a body, wherein the infusion device includes a processor;

a bolus estimator that utilizes externally supplied values to estimate an amount of fluid to be infused based upon an estimate of a material to be ingested by the body; and

a programmer for interfacing with the bolus estimator, the programmer including:

at least one processor to interface with the bolus estimator to process data for the bolus estimator;

a housing adapted to contain the at least one processor;

at least one display including at least one touch screen element to interface with at least one of the at least one processor and the bolus estimator;

at least one button to interface with at least one of the at least one processor and the bolus estimator;

at least one audio indication device coupled to the at least one processor to provide an audio indication; and

at least one portable power supply contained within the housing of the programmer to provide power to at least one of the at least one processor; and

wherein the externally supplied values for the bolus estimator are input into the programmer using either the at least one button or at least one touch screen element to estimate the amount of fluid to be infused. --

--57. An external infusion system according to claim 56, wherein the bolus estimator includes the capability to calculate a correction bolus based upon a current characteristic value and a target characteristic value. --

--58. An external infusion system according to claim 57, wherein the bolus estimator includes a liquid sensitivity that is used to determine the amount of fluid to be infused to calculate the correction bolus. --

--59. An external infusion system according to claim 58, wherein the fluid to be infused is insulin, and where the material to be taken in are carbohydrates. --

--60. An external infusion system according to claim 56, wherein the fluid to be infused is insulin, and where the material to be taken in are carbohydrates. --

--61. An external infusion system according to claim 56, wherein the bolus estimator includes a lockout to prevent the calculation of a bolus for a predetermined period of time after a bolus estimated by the bolus estimator. --

--62. An external infusion system according to claim 56, wherein the externally supplied values are codes representing a carbohydrate value of specific foods. --

--63. An external infusion system according to claim 56, wherein the externally supplied values are codes representing a carbohydrate value of specific meals. --

--64. An external infusion system according to claim 56, further including a duration factor to determine a value of how long a previously infused amount of fluid will remain active in the body, wherein the determined value is used to adjust the amount of the fluid to be infused into the body. --

--65. A method of estimating a bolus for an infusion system for infusion of a fluid into a body, the method comprising the steps of:

providing externally supplied values to estimate an amount of fluid to be infused based upon an estimate of a material to be ingested by the body; and

providing a programmer for interfacing with the externally supplied values, the programmer including:

at least one processor to utilize the externally supplied values;

a housing adapted to contain the at least one processor;

at least one display including at least one touch screen element to interface with at least one of the at least one processor;

at least one button to interface with at least one of the at least one processor;

at least one audio indication device coupled to the at least one processor to provide an audio indication; and

at least one portable power supply contained within the housing of the programmer to provide power to at least one of the at least one processor; and inputting the externally supplied values into the programmer using either the at least one button or at least one touch screen element; and

calculating an estimate of the amount of fluid to be infused. --

--66. A method according to claim 64, further comprising the step of calculating a correction bolus based upon a current characteristic value and a target characteristic value. --

--67. A method according to claim 66, further comprising the step of using a liquid sensitivity to determine the amount of fluid to be infused to calculate the correction bolus. --

--68. A method according to claim 67, wherein the fluid to be infused is insulin, and where the material to be taken in are carbohydrates. --

--69. A method according to claim 65, wherein the fluid to be infused is insulin, and where the material to be taken in are carbohydrates. --

--70. A method according to claim 65, further comprising the step of using a lockout to prevent the calculation of a bolus for a predetermined period of time after a bolus estimated by the bolus estimator. --

--71. A method according to claim 65, wherein the externally supplied values are codes representing a carbohydrate value of specific foods. --

--72. A method according to claim 65, wherein the supplied values are codes representing a carbohydrate value of specific meals. --

--73. A method according to claim 65, further comprising the step of using a duration factor to determine a value of how long a previously infused amount of liquid will remain active in the body, and using the determined value is to adjust the amount of the fluid to be infused. --

## REMARKS

Prior to examination of this preliminary application, the applicants respectfully request entry and consideration of the above amendments and following remarks. By virtue of this preliminary amendment, claims 56-73 are pending, claims 1-55 have been canceled without prejudice or disclaimer, and new claims 56-73 have been added. Consideration and allowance of all of the claims in view of the above amendments and the following remarks are respectfully requested.

Claims 1-55 have been canceled without prejudice or disclaimer, since canceled claims correspond to claims 1-55 in co-pending U.S. Patent Application Serial No. 09/334,858, filed on June 16, 1999, and entitled "External Infusion Device with Remote Programming, Bolus Estimator and/or Vibration Alarm Capabilities," in which the applicants are pursuing the subject matter of canceled claims 1-55. Accordingly, claims 1-55 are not being cancelled for reasons of patentability, as described in the recent Festo case.

Claims 56-73 have been added by this amendment. No new matter has been added. Support for the new claims can be found on pages 9, 10, 12-19 and 25-38 of the instant application. It is respectfully submitted that claims 56-73 are in condition for allowance.

Examination and consideration of the application, as amended, are requested.



**Pending Claims**

56. An external infusion system for infusion of a fluid into a body, the external infusion system comprising:

an infusion device for infusion of a fluid into a body, wherein the infusion device includes a processor;

a bolus estimator that utilizes externally supplied values to estimate an amount of fluid to be infused based upon an estimate of a material to be ingested by the body; and

a programmer for interfacing with the bolus estimator, the programmer including:

at least one processor to interface with the bolus estimator to process data for the bolus estimator;

a housing adapted to contain the at least one processor;

at least one display including at least one touch screen element to interface with at least one of the at least one processor and the bolus estimator;

at least one button to interface with at least one of the at least one processor and the bolus estimator;

at least one audio indication device coupled to the at least one processor to provide an audio indication; and

at least one portable power supply contained within the housing of the programmer to provide power to at least one of the at least one processor; and

wherein the externally supplied values for the bolus estimator are input into the programmer using either the at least one button or at least one touch screen element to estimate the amount of fluid to be infused.

57. An external infusion system according to claim 56, wherein the bolus estimator includes the capability to calculate a correction bolus based upon a current characteristic value and a target characteristic value.



58. An external infusion system according to claim 57, wherein the bolus estimator includes a liquid sensitivity that is used to determine the amount of fluid to be infused to calculate the correction bolus.

59. An external infusion system according to claim 58, wherein the fluid to be infused is insulin, and where the material to be taken in are carbohydrates.

60. An external infusion system according to claim 56, wherein the fluid to be infused is insulin, and where the material to be taken in are carbohydrates.

61. An external infusion system according to claim 56, wherein the bolus estimator includes a lockout to prevent the calculation of a bolus for a predetermined period of time after a bolus estimated by the bolus estimator.

62. An external infusion system according to claim 56, wherein the externally supplied values are codes representing a carbohydrate value of specific foods.

63. An external infusion system according to claim 56, wherein the externally supplied values are codes representing a carbohydrate value of specific meals.

64. An external infusion system according to claim 56, further including a duration factor to determine a value of how long a previously infused amount of fluid will remain active in the body, wherein the determined value is used to adjust the amount of the fluid to be infused into the body. —

65. A method of estimating a bolus for an infusion system for infusion of a fluid into a body, the method comprising the steps of:

providing externally supplied values to estimate an amount of fluid to be infused based upon an estimate of a material to be ingested by the body; and

providing a programmer for interfacing with the externally supplied values, the programmer including:

at least one processor to utilize the externally supplied values;  
a housing adapted to contain the at least one processor;

at least one display including at least one touch screen element to interface with at least one of the at least one processor;

at least one button to interface with at least one of the at least one processor;

at least one audio indication device coupled to the at least one processor to provide an audio indication; and

at least one portable power supply contained within the housing of the programmer to provide power to at least one of the at least one processor; and

inputting the externally supplied values into the programmer using either the at least one button or at least one touch screen element; and

calculating an estimate of the amount of fluid to be infused.

66. A method according to claim 64, further comprising the step of calculating a correction bolus based upon a current characteristic value and a target characteristic value.

67. A method according to claim 66, further comprising the step of using a liquid sensitivity to determine the amount of fluid to be infused to calculate the correction bolus.

68. A method according to claim 67, wherein the fluid to be infused is insulin, and where the material to be taken in are carbohydrates.

69. A method according to claim 65, wherein the fluid to be infused is insulin, and where the material to be taken in are carbohydrates.

70. A method according to claim 65, further comprising the step of using a lockout to prevent the calculation of a bolus for a predetermined period of time after a bolus estimated by the bolus estimator.

71. A method according to claim 65, wherein the externally supplied values are codes representing a carbohydrate value of specific foods.

72. A method according to claim 65, wherein the supplied values are codes representing a carbohydrate value of specific meals.

73. A method according to claim 65, further comprising the step of using a duration factor to determine a value of how long a previously infused amount of liquid will remain active in the body, and using the determined value is to adjust the amount of the fluid to be infused.